

REMARKS

Status of the Claims.

Claims 1-22 are pending with entry of this amendment. Claim 1 is amended herein to clarify that the library is an aqueous composition, e.g., that includes all members of the library as opposed to individual nucleic acids, e.g., arrayed on a surface, and to clarify that every nucleic acid probe in the library is a specified transcription factor probe. No new matter is added by this amendment and Applicants respectfully request that the amendments be entered.

Claims 1-22 were rejected for alleged obviousness. Applicants traverse all rejections for the reasons of record, and, additionally, for the reasons noted herein.

THE CLAIMS ARE NOT OBVIOUS OVER THE ART

The Examiner rejected claims 1-22 under 35 U.S.C. §103(a) for alleged obviousness over Kauffman in view of Morris. Applicants traverse and amend for clarity. Claims 1-22 were also rejected under 35 U.S.C. §103(a) for alleged obviousness over Li in view of Morris. Applicants traverse and amend the claims for clarity.

A finding of obviousness requires a determination of whether “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 USC § 103(a). As the Federal Circuit has repeatedly indicated, this inquiry ultimately involves determining “whether a person of ordinary skill would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so.” *Dystar Textilfarben GmbH v. C.H. Patrick Co.* 80 USPQ2d 1641 at 1645 (Fed. Cir. 2006).

The Supreme Court recently cautioned that the question of motivation to combine the prior art must be approached with “common sense,” rather than as a rigid formula:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or

her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

KSR International Co. V. Teleflex inc. et al. 550 U. S. ____ (2007) slip opinion page 6.

However, the reverse is also true, i.e., as the Federal Circuit has recently emphasized, where there are “not the easily traversed, small and finite number of alternatives that KSR suggested,” a finding of obviousness is not supported. Ortho-MacNeil Pharmaceutical, Inc. v. Mylan L, inc., and Mylan Pharmaceuticals, inc. (Slip opinion at pages 9-10, Fed Cir. published March 31, 2008). This is consonant with (and really just a restatement of) the long standing requirement that there be a “reasonable expectation of success” in achieving a claimed invention *arising from the prior art* before the invention can be considered obvious. MPEP 2143. The requisite set of “identified predictable solutions”/ “reasonable expectation of success” is simply missing in the present case.

The Federal Circuit also explained in Ortho-McNeil, that “the ordinarily skilled artisan would have to have some reason to select (**among several unpredictable alternatives**) the exact route that produced” the claimed invention. This is simply not possible without an “easily traversed, small and finite number of alternatives that KSR suggested might support an inference of obviousness.” Slip opinion, Page 9.

In other words, the court refused to accept that an invention could be obvious when the rejection “simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention . . . was obvious.” Ortho-McNeil Slip opinion, Page 9. The Federal Circuit emphasized that a pathway to the invention that seems to follow the logical steps in retrospect, is not sufficient for a determination of obviousness. Ortho-McNeil was a biotechnology case much more similar to the instant case than the simple mechanical issues of KSR, making the reasoning applicable in the instant case as well.

In the present application, the options in biotechnology, and transcription factor analysis in particular, are too vast and too unpredictable to support a conclusion of obviousness. Furthermore, even if many of the individual elements of the presently claimed invention are found in the prior art as well as a desire to identify transcription factors, the art must contain some suggestion or motivation to combine these elements **in the manner claimed** because the

universe of possibilities in transcription factor analysis is huge, i.e., not finite, identifiable, and predictable as required for an obvious determination. Therefore, some suggestion must be presented as to why one of skill would have selected the claimed combination from all the possible elements present in the art.

The action alleged that Kauffman and Morris teach a library of nucleic acid constructs as claimed and that because both references address expression methods and a need for high throughput methods it was obvious to combine them to produce the claimed invention. However, this argument does not address the fact that each and every construct in the claimed library comprises a cis element "to which a **specified** transcription factor is **known** to bind" and that each construct comprises two corresponding variable regions: each cis element/transcription factor pair corresponds to a different reporter sequence. This is clarified by amending the "comprising" language to "consisting essentially of." Therefore the claims are not obvious over Kauffman and Morris.

The action alleged that Li renders the claimed invention obvious in view of Morris. However, Li does not teach a composition comprising the library as claimed. The constructs in Li are individual constructs not contained within an aqueous composition as claimed. And although Li mentions different reporters that can be used, the individual constructs of Li that are alleged to be the "library" all comprise the same reporter, see, e.g., Figure 4. No correspondence between a particular cis element and reporter is found in Li and even when combined with Morris, no composition comprising a library as claimed can be found. Therefore, the claims are not obvious over Li and Morris.

Both combinations of references fail to establish the Office's burden of persuasion on the issue of obviousness. Indeed, no case for obviousness can properly be made out at all. The amended claims clarify that the library is an aqueous composition consisting essentially of a library of specific known transcription factor probes. These clarifying amendments make the rejection moot as the action has not addressed an aqueous solution or a library of probes wherein every member is a known transcription factor probe.

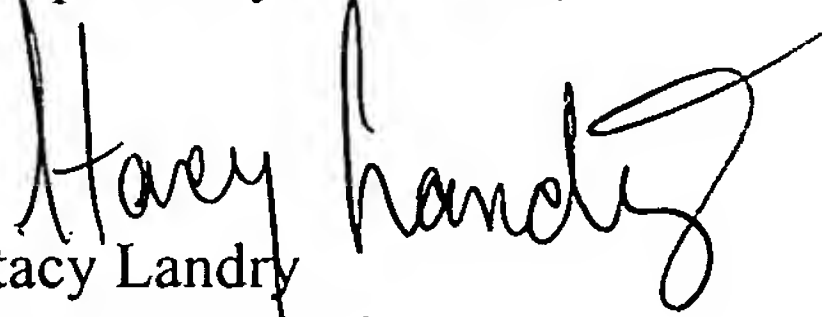
Appl. No. 10/057,828
Response Dated 1/8/2009
Reply to Office action of July 8, 2008

CONCLUSION

The claims are in condition for allowance. A notice of allowance at an early date is, therefore respectfully requested. If the claims are deemed not to be in condition for allowance after consideration of this Response, please telephone the undersigned at (510) 337-7871 to schedule an interview.

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Respectfully submitted,


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Attachments:

- 1) A petition to extend the period of response for 3 months;
- 2) A request for continued examination;
- 3) A transmittal sheet;
- 4) A fee transmittal sheet; and
- 5) A receipt indication postcard.